NOV - 8 2004

K042153

APPENDIX B

510(k) PREMARKET NOTIFICATION SUMMARY

(Per 21 CFR 807.92)

DENTOVATIONS INC.

SOUTH BEACH SMILE LIGHT WHITENING SYSTEM

I. Applicant:

Dentovations Inc.
8 Faneuil Hall Marketplace, 3rd Floor
Boston, MA 02109

Key Contact: M. Joyce Heinrich
Texas Applied Biomedical Services, Inc.
12101 Cullen Blvd., # A
Houston, Texas 77047
713 / 734-4433 telephone
713 / 734-5671 facsimile
Email: tabsii@msn.com

II. Device Name

Proprietary Name:	South Beach Smile Light Whitening System
Common / Usual Name:	Whitening Light System
Classification Name:	Heat source for bleaching teeth (21 CFR 872.6475)
Product Code:	EEB

III. Predicate Device

The Dentovations Inc. South Beach Smile Light Whitening System is substantially equivalent to other tooth whitening lights currently in commercial distribution such as the BriteSmile and Dental ZOOM Light.

IV. Intended Use of the Device

The South Beach Smile Light Whitening System is intended to emit light in the 350 – 700 nanometer spectrums to provide a heat source for bleaching of teeth.

V. Description of the Device

The South Beach Smile Light Whitening System is intended for use by the consumer and sold either over the counter or by a dental professional as a tooth whitening system. The System consists of a handheld, battery operated light (heat source) device, a whitening gel and preconditioning mouth wash.

The Whitening Light heat source is a hand held device that contains a biologically safe and effective level of blue visible light, which can penetrate the tooth and activate the photoactive substances within the tooth yielding a minimal amount of heat. The general wavelength is 350 -700 nm. The xenon light emits approximately 1°- 3° C heat against the tooth surface. To insure user safety when operating the light, the light has built in features that will eliminate any risk for the end user (1) light automatically shuts off after two minutes of use and (2) the light head acts a lip retractor and light guard to prevent any light from accidentally being exposed to the users eyes. The Whitening Light has been tested and proven to be safe for the consumer to use.

VI. Summary of the Technical Characteristics of the South Beach Smile Light Whitening System as Related to the Referenced Predicate Devices.

The Dentovations Inc. South Beach Smile Light Whitening System and the aforementioned predicate devices are heat source for bleaching teeth as defined in 21 CFR 898.6475.

The South Beach Smile Light Whitening System is an economical tooth whitening light which in conjunction with the whitening gel and tooth whitening preconditioning mouth wash provides a heat source for bleaching teeth. The South Beach Smile Light Whitening System has similar intended use and technological characteristics to the predicate devices. The primary difference is the South Beach Smile Light Whitening System is proposed for use by the consumer and dental professions. Due to its low intensity light, the South Beach Smile Light Whitening System, is safer to user than other traditional heat sources for bleaching teeth.

VII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the Dentovations Inc. South Beach Smile Light Whitening System has the same intended use, with similar functional and performance characteristics. The Dentovations Inc. South Beach Smile Light Whitening System performs as intended and does not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2004

Dentovations, Incorporated
C/O Ms. M. Joyce Heinrich
Regulatory Consultant
Texas Applied Biomedical Services
12101 Cullen Boulevard, Suite A
Houston, Texas 77047-2951

Re: K042153
Trade/Device Names: South Beach Smile Light Whitening System
Regulation Number: 21 CFR 872.6475
Regulation Name: Heat Source for Bleaching Teeth
Regulatory Class: I
Product Code: EEG
Dated: August 06, 2004
Received: August 13, 2004

Dear Ms. Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

In addition, we have determined that your device contains the following component whose regulatory status has not yet been determined: urea peroxide. In late 1991, the Food and Drug Administration sent letters to manufacturers and/or distributors of tooth whitening preparations (such as the bleaching gel contained in your device) advising them that the agency considered the product drugs and "new drugs" as defined in the Federal Food, Drug, and Cosmetic Act (the act). Under the provisions of the act, a "new drug" may not be legally marketed in this country unless it is the subject of an approved New Drug Application (NDA). The NDA must contain adequate scientific data, including clinical trials, which establish that a product is safe and effective for its intended use.

As a result of a court case brought by one of the manufacturers, the agency agreed to further evaluate the status of tooth whitener preparations to determine whether they should be regulated as "new drugs" or cosmetics. The agency has not yet completed that further evaluation. The status of urea peroxide, the whitening component of your device, is unresolved at this time.

Our substantially equivalent determination does not apply to the whitening component(s) of your device.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other

general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX C

Indications for Use

510(k) Number (if known): K042153

Device Name: **South Beach Smile Light Whitening System**

Indications for Use:

The Dentovations South Beach Smile Light Whitening System is intended for use as a light source for bleaching teeth.

Prescription Use: _____ **AND/OR** **Over the Counter Use:** X
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODpE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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